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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,413	10/26/2006	Toshihiko Ohtomo	14875-164US1 CI-A0321P-US	7418
26161	7590	03/11/2009	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			DUFFY, BRADLEY	
			ART UNIT	PAPER NUMBER
			1643	
			NOTIFICATION DATE	DELIVERY MODE
			03/11/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,413	<b>Applicant(s)</b> OHTOMO ET AL.	
	<b>Examiner</b> BRADLEY DUFFY	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-59 is/are pending in the application.
- 4a) Of the above claim(s) 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 40-54 and 59 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment filed November 17, 2008, is acknowledged and has been entered. Claims 1-19 have been canceled. Claims 40-59 have been newly added.
2. The amendment filed December 17, 2008, is acknowledged and has been entered. Claims 40, 41 and 59 have been amended.
3. Claims 40-59 are pending. Claims 55-58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
4. Claims 40-54 and 59 are currently subject to a requirement to elect a species of invention, as has been necessitated by the addition of new claims 47 and 48, which are directed to a plurality of species of the elected invention of Group I.

### ***Election/Restrictions***

5. The amendment filed December 17, 2008, presents claims 55-58, which are directed to an invention that lacks unity with the originally elected invention for the following reasons:

In this case, the methods of claims 55-58 do not relate to the same single general inventive concept under PCT Rule 13.1 as the method of originally elected claim 59, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

Notably, as set forth in the restriction requirement mailed January 4, 2008, the technical feature recited in claim 1 is enhancing the activity of an antibody by making the antibody into a single-chain polypeptide comprising two or more light chain variable regions and two or more heavy chain variable regions which lacks inventive step in view of Fukushima, et al. (US PG PUB 2004/0058393, PCT filed April 17, 2001). Accordingly,

it is submitted that the methods set forth in claims 55-58 do not share the same technical feature as the elected invention.

In this case, the processes set forth in claims 55-58 lack the intended use of enhancing the activity of an antibody of the elected invention, and require *two* different antibodies with bind different epitopes while the elected invention made *the* antibody into a single-chain polypeptide comprising two or more light chain variable regions and two or more heavy chain variable regions.

Therefore, it is apparent that claims 55-58 are drawn to methods that have a different special technical feature than the special technical feature of the elected invention because claims 55-58 do not recite the method objective of the elected invention and require two antibodies, while the elected invention enhances the activity of a singular antibody. Therefore, it is submitted that the methods of claims 55-58 do not relate to the same single general inventive concept under PCT Rule 13.1 as the elected invention. Furthermore, it is noted that PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product. Accordingly, the methods set forth in claims 55-58 do not form a single general inventive concept with the original elected method.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-58 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant is further reminded that applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims which the examiner holds are drawn to an invention other than the one elected (see MPEP § 819 and 821.03).

6. This application contains claims directed to the patentably distinct species of the elected invention.

The elected invention is the invention of Group I, drawn to a method of

Art Unit: 1643

enhancing the activity of an antibody by making the antibody into a single-chain polypeptide comprising two or more light chain variable regions and two or more heavy chain variable regions. Accordingly, previously presented claims examined in this application were directed to a plurality of antibodies which bound a plurality of antigens.

As newly presented and amended, claim 40 is generic to a plurality of species of the elected invention, wherein said antigen is selected from the group consisting of: members of the hematopoietic factor receptor family, members of the cytokine receptor family, members of the tyrosine kinase receptor family, members of the serine/threonine kinase receptor family, members of the tumor necrosis factor (TNF) receptor family, members of the G protein-coupled receptor family, members of the glycosylphosphatidylinositol (GPI)-anchored receptor family, members of the tyrosine phosphatase receptor family, members of the adhesion factor family, members of the hormone receptor family, myeloproliferative leukemia virus oncogene (mpl), erythropoietin (EPO) receptor, TPO receptor, granulocyte colony-stimulating factor (G-CSF) receptor, growth hormone (GH) receptor, insulin receptor, Flt-3 ligand receptor, platelet-derived growth factor (PDGF) receptor, interferon (IFN)- $\alpha$  receptor, IFN $\beta$  receptor, leptin receptor, interleukin (IL)-10 receptor, insulin-like growth factor (IGF)-I receptor, leukemia inhibitory factor (LIF) receptor, and ciliary neurotrophic factor (CNTF) receptor.

M.P.E.P. § 808.01(a) states: "If applicant presents species claims to more than one patentably distinct species of the invention after an Office action on only generic claims, with no restriction requirement, the Office may require the applicant to elect a single species for examination". See M.P.E.P. §§ 811.02 and 818.02(b).

These species of the elected invention are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In this case, the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Notably, PCT Rule 13.2 sets forth that alternatives claimed in the same claim are linked by a special technical feature when the alternatives are of a similar nature. PCT

Art Unit: 1643

Rule 13.2 further sets forth that alternatives are of a similar nature when:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In this case, while the each of the species of antigen are receptors, each is a structurally and functionally different receptor antigen which comprises different amino acid sequences, respectively. Accordingly, the species of antigen are not of a similar nature because they all do not share a significant structural element and because they all do not belong to the same recognized class of chemical compound in the art.

For these reasons, each method of the elected invention drawn to a species of antigen set forth above is not deemed to share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

Art Unit: 1643

added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or clearly identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. Applicant is further reminded that a generic claim may be allowable over the prior art, but not necessarily over 35 U.S.C. 101 and 112.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1643

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Brad Duffy  
571-272-9935

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

/bd/  
Examiner, Art Unit 1643  
March 5, 2009